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K042376
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510(k) Summary

General Information

Date Compiled	August 30, 2004
Classification	Class II
Trade Name	Acumen Sheath
Submitter	Acumen Medical, Inc. 1400 Terra Bella Blvd. Suite A Mountain View, CA 94043
Contact	Marybeth Gamber Director, Regulatory Affairs tel: 650-352-5700, ext. 226 fax: 650-352-5700

Intended Use

The Acumen Sheath is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

Predicate Devices

SafeSheath Coronary Sinus Guide K003731

Manufactured by Pressure Products, Inc/Thomas Medical Products Inc.

Device Description

The Acumen Sheath is a single-use percutaneous catheter indicated for the introduction of various types of pacing or defibrillator leads and catheters.

The Acumen Sheath has a guidewire lumen and a lumen for the introduction of various types of pacing or defibrillator leads and catheters. The delivery lumen is coated with a lubricious coating to aid in device delivery. The sheath is designed to be splittable, thereby allowing its removal from the lead, and a slitter is provided with the device.

Materials

All materials used in the manufacture of the Acumen Sheath are suitable for this use and have been used in numerous previously cleared products.

Testing

In-vitro and *in-vivo* testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

Summary of Substantial Equivalence

Acumen Medical believes the Acumen Sheath is substantially equivalent to the predicate product. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2004

Acumen Medical, Inc.
c/o Ms. Marybeth Gamber
Director, Regulatory Affairs
1400 Terra Bella Blvd., Suite A
Mountain View, CA 94043

Re: K042376
Trade Name: Acumen Sheath, Model TTW 7807
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 30, 2004
Received: September 1, 2004

Dear Ms. Gamber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4591. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	This application
Device Name:	Acumen Sheath
Indications for Use:	The Acumen Sheath is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

Prescription Use _X_ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042376